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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,566	09/14/2001	Naoki Tsuchiya	Q66152	8705

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,566

Applicant(s)

TSUCHIYA ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1 and 4-21 are pending in the application.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicants' amendment to the claims or by the submission of certified English translations of the priority documents. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 20, the phrase "set forth in any one Claims 1 and 4 to 9" should have read "set forth in any one of Claims 1 or 4 to 9".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over claims 1, 2, 4-6, 8-11, 13 and 15 of copending Application No. 09/743,483. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims in application '483 differ only by generic description of the products. See, for example, claim 1 in application '483 and especially compound 444 in Table 18 on page 33.

One skilled in the art would thus be motivated to prepare products embraced by application '483 to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful as human chymase inhibitors. Therefore, the instant claimed products would have been suggested to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants' arguments filed September 30, 2003 have been fully considered. In regard to the rejection of the claims under an obviousness-type double patenting rejection, Applicants state that they will hold the rejection in abeyance until allowable subject matter is indicated in one of the two applications.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-10, 12 and 14-21 are rejected under 35 U.S.C. 102(b) as being anticipated by:

- a) Yoshida et al. {JP 03-014566 or CA 115:71600, 1991} – see CA Registry No. 134464-63-4;
- b) Nicolai et al. {Journal of Medicinal Chemistry (1993), 36(9), pages 1175-1187} – see, for example, Tables IV, V and VI on pages 1181, 1182 and 1183, respectively, compounds 7a, 7b, 7c, etc.;
- c) Bru-Magniez et al. {U.S. Pat. 5,021,443} – see, for example, Example 63 in column 29;
- d) Bru-Magniez et al. {U.S. Pat. 5,124,336} – see, for example, Example 59 in column 41; and
- e) Bru-Magniez et al. {U.S. Pat. 5,128,359} – see, for example, Example 64 in column 41.

Each of the above cited prior art disclose products embraced by the instant claims.

Response to Arguments

Applicants' arguments filed September 30, 2003 have been fully considered. In regard to the rejection of the claims under 35 USC § 102(b), Applicants argue that none of the cited references teaches or suggests that the compounds have human chymase inhibiting activity.

In response, the prior art teaches the same compounds as Applicants are claiming. The prior art teaches treating the same diseases/disorders that Applicants claim that their compounds treat. For example, instant claim 20 states that the respiratory diseases and cardiovascular diseases are targeted by inhibiting human chymase activity. In Nicolai et al., for example, teach that the benzimidazole compounds can treat cardiovascular and respiratory diseases (page 1175, column 1, first paragraph). Further, as noted above, Nicolai et al. discloses compounds that are embraced by the instant claims. A compound and its properties are inseparable. *In re Papesch*, 137 USPQ 43 (CCPA 1963). The rejection is deemed proper and therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-10, 12 and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bru-Magniez et al. {U.S. Pat. 5,021,443}, Bru-Magniez et al. {U.S. Pat. 5,124,336} and Bru-Magniez et al. {U.S. Pat. 5,128,359}, each taken alone or in combination with each other when similar utilities are asserted.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim benzimidazole products. Bru-Magniez et al. '443 (columns 1, 2 and 11 ; or Example 63 in column 29), Bru-Magniez et al. '336 (columns 1, 2, 11 and 12 ; or Example 59 in column 41) and Bru-Magniez et al. '359 (columns 1, 2, 11 and 12 ; or Example 64 in column 41) each teach benzimidazole products which are either structurally the

same as (see above 102 rejections) or structurally similar to the instant claimed products.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between some of the products of the prior art and the products instantly claimed is that the instant claimed products are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of “some” among “many” is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed products derives from the expectation that structurally similar products would possess similar activity (e.g., thromboxane receptor antagonist – TXA₂).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products that would have thromboxane receptor antagonist properties and which would be

useful in treating diseases/disorders such as myocardial infarction, angina pectoris, pulmonary embolism, asthma, bronchitis, etc. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicants' arguments filed September 30, 2003 have been fully considered. In regard to the rejection of the claims under 35 USC § 103, Applicants argue that the compounds in Bru-Magniez et al. '443 (Example 63 in column 29), Bru-Magniez et al. '336 (Example 59 in column 41) and Bru-Magniez et al. '359 (Example 64 in column 41) are excluded per the proviso found in instant claim 10.

Applicants' arguments have been considered but have not been found persuasive. The proviso at the end of independent claim 10 states, "provided that when at least one of X¹ and X² is a cyano group,

$-\text{CH}_2\text{NH}_2$, $-\text{CH}=\text{NR}^1$, $-\text{CH}=\text{NOR}^1$ or $-\text{CONR}^1\text{R}^2$ (here, R^1 and R^2 are each a hydrogen atom or a C_{1-4} alkyl group), J expresses only a substituted naphthalene ring". Hence, compounds wherein X^1 and X^2 , independently, are hydrogen or halogen are not excluded by the proviso. The rejection is deemed proper and therefore, the rejection is maintained.

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

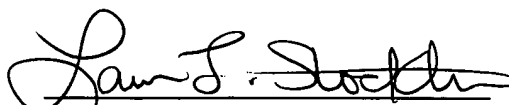
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

January 14, 2004